UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/871,282	05/31/2001	Philip Shi-Lung Yu	YOR920010300US1	8621

35526 7590 03/06/2006

DUKE. W. YEE
YEE & ASSOCIATES, P.C.
P.O. BOX 802333
DALLAS, TX 75380

EXAMINER	
TOMASZEWSKI, MICHAEL	
ART UNIT	**PAPER NUMBER**
3626	

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/871,282	YU ET AL.	
	Examiner	Art Unit	
	Mike Tomaszewski	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 May 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice To Applicant

1. This communication is in response to the application filed on 12 December 2005. Claims 1-15 are pending. Claims 16-21 have been cancelled.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 3, 8, 10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bouthiette (5,788,079; hereinafter Bouthiette), in view of Mayaud (5,845,255; hereinafter Mayaud)

(A) Claim 1 has been amended to recite the following:

"wherein grouping medications into dosage groups comprises checking a database for at least one of a potential interaction between one element of

medication and other elements of medication in a same dosage group or a recommendation to not take one element of medication with other elements of medication in the same dosage group;"

Although Bouthiette fails to expressly disclose this feature, this feature is old and well known in the art, as evidenced by Mayaud. In particular, Mayaud discloses a method of packaging medications on demand, the method comprising:

grouping medications into dosage groups, wherein grouping medications into dosage groups comprises checking a database for at least one of a potential interaction between one element of medication and other elements of medication in a same dosage group or a recommendation to not take one element of medication with other elements of medication in the same dosage group (Mayaud: abstract; col. 28, line 49-col. 32, line 14; fig. 1-21).

Examiner respectfully submits that the cited Mayaud passages expressly teach grouping medications into dosage groups, as do the various accompanying figures, namely Figure 15. Examiner also takes note that Bouthiette teaches grouping medications into dosage groups as well, as illustrated by Figure 8 of Bouthiette. Moreover, the cited Mayaud passages further teache a robust and comprehensive drug contraindications system whereby, *inter alia*, a drug database is queried to assess drug-to-drug interactions between different drug elements.

One of ordinary skill would have found it obvious at the time of the invention to combine the teachings of Mayaud with the teachings of Bouthiette with the motivation of

providing a computerized prescription management system to assist physicians in prescribing and reviewing drugs (Mayaud: col. 1, lines 15-18).

The remaining features of claim 1 are rejected for the reasons set forth in the previous Office Action, and incorporated herein.

(B) Claims 3, 8, 10 and 15 are rejected for the same reasons set forth in Claim 1, *supra*, and for the same reasons set forth in the previous Office Action, and incorporated herein.

4. Claims 2 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bouthiette and Mayaud as applied to claims 1 and 8 above, and further in view of Machblitz (4,429,792; hereinafter Machblitz).

(A) Claims 2 and 9 are rejected for the same reasons set forth in Claim 1, *supra*, and for the same reasons set forth in the previous Office Action, and incorporated herein.

5. Claims 4 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bouthiette and Mayaud as applied to claims 1 and 8 above, and further in view of Croce (4,762,230; hereinafter Croce).

(A) Claims 4 and 11 are rejected for the same reasons set forth in Claim 1, *supra*, and for the same reasons set forth in the previous Office Action, and incorporated herein.

6. Claims 5 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bouthiette and Mayaud as applied to claims 1 and 8 above, and further in view of Kobylevsky et al. (5,845,255; hereinafter Kobylevsky).

(A) Claims 5 and 12 are rejected for the same reasons set forth in Claim 1, *supra*, and for the same reasons set forth in the previous Office Action, and incorporated herein.

7. Claims 6-7 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bouthiette and Mayaud as applied to claims 1 and 8 above, and further in view of Sadler, Jr. et al. (4,830,407; hereinafter Sadler).

(A) Claims 6-7 and 13-14 are rejected for the same reasons set forth in Claim 1, *supra*, and for the same reasons set forth in the previous Office Action, and incorporated herein.

Response to Arguments

8. Applicant's arguments with respect to claims 1-15 concerning the amended feature (i.e., "...wherein first instructions for instructing the medication packager to group medications into dosage groups comprises second instructions to check a database for at least one of a potential interaction...") have been considered but are moot in view of the new ground(s) of rejection.

9. Applicant's arguments filed on 12 December 2005 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 12 December 2005.

(A) On page 13 of the 12 December 2005 response, Applicant argues Machblitz does not cure the deficiencies in Bouthiette.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Examiner has assessed Applicant's claimed invention as obvious based on the combined teachings of Machblitz, Bouthiette and general knowledge of one of ordinary skill in the art. Whereas Machblitz teaches, *inter alia*, the limitation of "blister packs" or

"foil packs." Bouthiette teaches, *inter alia*, the limitation of incorporating a dosage group within an individual compartment (Bouthiette: Fig. 8; Note the two distinct medications or multiple doses of medication or dosage group.).

As per Applicant's argument that "neither Bouthiette nor Machblitz teaches the problem of the present invention or its source," Examiner respectfully submits that this argument is not persuasive in view of *In re Oetiker*, 977 F.2d 1443, 1446, 24, USPQ2d 1443, 1445 (Fed. Cir. 1992). More specifically, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, both Bouthiette and Machblitz fall within the field of Applicant's endeavor, namely, pharmaceutical packaging. In addition, both Bouthiette and Machblitz are reasonably pertinent to the particular problem with which the Applicant was concerned, that is, problems relating to correct pharmaceutical dispensing (See Bouthiette: abstract; col. 1, lines 10-19; and Machblitz: abstract; col. 1, lines 10-24).

Correlated arguments pertaining to Claim 2 and 9 have been rendered moot in view of the new ground(s) of rejection via Mayaud.

(B) On page 14 and 15 of the 12 December 2005 response, Applicant argues Croce does not cure the deficiencies in Bouthiette.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Examiner has assessed Applicant's claimed invention as obvious based on the combined teachings of Croce, Bouthiette and general knowledge of one of ordinary skill in the art. Whereas Croce teaches, *inter alia*, the limitation of a food item within a compartment, Bouthiette teaches, *inter alia*, the concept of incorporating a dosage group within an individual compartment (Bouthiette: Fig. 8; Note the two distinct medications or multiple doses of medication or dosage group.).

As per Applicant's argument that "neither Bouthiette nor Croce teaches the problem of the present invention or its source," Examiner respectfully submits that this argument is not persuasive in view of *In re Oetiker*, 977 F.2d 1443, 1446, 24, USPQ2d 1443, 1445 (Fed. Cir. 1992). More specifically, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, both Bouthiette and Croce fall within the field of Applicant's endeavor, namely, pharmaceutical packaging. In addition, both Bouthiette and Croce are reasonably pertinent to the particular problem with which the Applicant was concerned, that is,

problems relating to correct pharmaceutical dispensing (See Bouthiette: abstract; col. 1, lines 10-19; and Croce: abstract; col. 6, lines 29-36).

Correlated arguments pertaining to Claim 4 and 11 have been rendered moot in view of the new ground(s) of rejection via Mayaud.

(C) On page 15 and 16 of the 12 December 2005 response, Applicant argues Kobylevsky does not cure the deficiencies in Bouthiette.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Examiner has assessed Applicant's claimed invention as obvious based on the combined teachings of Kobylevsky, Bouthiette and general knowledge of one of ordinary skill in the art. Whereas Kobylevsky teaches, *inter alia*, the limitation transmitting an order for medication to a pharmacy via a network, Bouthiette teaches, *inter alia*, the concept of incorporating a dosage group within an individual compartment (Bouthiette: Fig. 8; Note the two distinct medications or multiple doses of medication or dosage group.).

As per Applicant's argument that "neither Bouthiette nor Kobylevsky teaches the problem of the present invention or its source," Examiner respectfully submits that this argument is not persuasive in view of *In re Oetiker*, 977 F.2d 1443, 1446, 24, USPQ2d 1443, 1445 (Fed. Cir. 1992). More specifically, it has been held that a prior art

reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, both Bouthiette and Kobylevsky fall within the field of Applicant's endeavor, namely, pharmaceutical packaging and pharmaceutical transactions, respectively. In addition, both Bouthiette and Kobylevsky are reasonably pertinent to the particular problem with which the Applicant was concerned. Whereas the former, Bouthiette, is reasonably pertinent to the problems relating to correct pharmaceutical dispensing (See Bouthiette: abstract; col. 1, lines 10-19), the latter, Kobylevsky, is reasonably pertinent to the problems relating to pharmaceutical transactions (Kobylevsky: abstract; col. 1, lines 5-12).

Correlated arguments pertaining to Claim 5 and 12 have been rendered moot in view of the new ground(s) of rejection via Mayaud.

(D) On page 17 and 18 of the 12 December 2005 response, Applicant argues Sadler does not cure the deficiencies in Bouthiette.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Examiner has assessed Applicant's claimed invention as obvious based on the

combined teachings of Sadler, Bouthiette and general knowledge of one of ordinary skill in the art. Whereas Sadler teaches, *inter alia*, the limitation of producing revised instructions to affix to the packaging, Bouthiette teaches, *inter alia*, the concept of incorporating a dosage group within an individual compartment (Bouthiette: Fig. 8; Note the two distinct medications or multiple doses of medication or dosage group.).

As per Applicant's argument that "neither Bouthiette nor Sadler teaches the problem of the present invention or its source," Examiner respectfully submits that this argument is not persuasive in view of *In re Oetiker*, 977 F.2d 1443, 1446, 24, USPQ2d 1443, 1445 (Fed. Cir. 1992). More specifically, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, both Bouthiette and Sadler fall within the field of Applicant's endeavor, namely, pharmaceutical packaging and pharmaceutical instructions, respectively. In addition, both Bouthiette and Sadler are reasonably pertinent to the particular problem with which the Applicant was concerned. Whereas the former, Bouthiette, is reasonably pertinent to the problems relating to pharmaceutical dispensing (See Bouthiette: abstract; col. 1, lines 10-19), the latter, Sadler; is reasonably pertinent to the problems relating to providing pharmaceutical instructions (Sadler: abstract; col. 1, lines 5-16).

Correlated arguments pertaining to Claims 6, 7, 13 and 14 have been rendered moot in view of the new ground(s) of rejection via Mayaud.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. The cited but not applied art teaches a medication dosage regulation apparatus (6,371,297); a product packaging material for individual temporary storage of pharmaceutical products (6,981,592); a medication compliance aid for unit dose packaging (4,617,557); a monitor board for pill-taking schedule (Des. 281,176); and a package assembly for dispensing pharmaceutical medications and method of manufacturing the same (5,014,851).

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mike Tomaszewski whose telephone number is (571)272-8117. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571)272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MT

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER